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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,489	04/30/2001	David Bach	20816/2	2352

7590

11/04/2004

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,489

Applicant(s)

BACH ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-89, 95-101 is/are rejected.
- 7) ☒ Claim(s) 90-94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 7/6/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-81 are cancelled.
2. Claim 82-101 are added to the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 86-94, 99, 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 86, line 3, "film strips comprise a width of 8 mm, 16mm or 32 mm" is vague and indefinite. It is not clear whether this "width" refers to the "thickness" of the film. Applicant needs to clarify. Similarly, claim 99 suffers the same problem.

With respect to claim 87, line 2, "wherein said film is rolled" is vague and confusion. It is not clear why this film structure is "rolled." Particularly, it is not clear what is the relationship of this "rolled" structure with respect to the detection device.

With respect to claim 89, line "3, "an intermediate protective cladding layer located between said polymer waveguide core and said waveguide cladding layer" is vague and confusion. It is not clear if this extra cladding layer would prevent the detection of the binding since the function of cladding layer is to confine the wave propagation. This

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extra cladding layer, in fact, would block the direct reflection of light to the detector (See Figure 1). Similarly, claim 101 suffers the same problem.

With respect to claim 90, "a laminar biosensor" is vague and indefinite. There is no definition for the term "laminar" in the specification. Applicant needs to clarify. Similarly, claims 91-94 suffer the same problem.

With respect to claim 90, line 1, "a top outer layer containing at least one fluid port" is vague and indefinite. It is not clear what is this top outer layer made of, either cladding layer or core-waveguide layer, or layer other than the former two. Applicant needs to clarify.

With respect to claim 94, line 2, "a bottom supporting layer" is vague and indefinite. Like the problem of "top outer layer" discussed before, applicant needs to clarify.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 82-83, 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson et al. (US 5835645) in view of Delmarche et al. (Science 1997 Vol. 276: 779).

Jorgenson et al. teach a fiber optical sensor for detection of target molecules in a sample. The sensor taught by Jorgenson comprises of a polymer core waveguide and a polymer cladding layer wherein the cladding layer can be removed a portion becoming a sensing area, e.g. nanowell, in contact with the core waveguide layer for detecting sample (See Figure 2 and Figure 3; Col. 3, line 8-22; Col. 6, line 45-55). Furthermore, Jorgenson et al. also teach adding reactive layers, including antigen or antibody bound to the sensing area for detection of binding pair molecules (Col. 8, line 35-42). The device also includes a light source optically coupled to the core layer where the light source creating an evanescent wave for detection of analyte (Col. 7, line 25-35). However, Jorgenson et al. do not explicitly teach (1) using plurality of nanowells in the cladding layers, (2) using plurality of micro-fluidic channels in communication with the nanowells for conveying samples.

Delamarche et al. teach a microfluidic network device comprising plurality of micro-fluidic channels conveying samples to plurality of waveguides (See page 779, Introduction; Figure 1A and 1C). The device provides advantages of time-saving, cost-effective and efficiency-increasing for analysis of multiple samples at the same time (Figure 1A and 1C). Additionally, the device taught by Delamarche et al. also can conveys fluorescently tagged IgG binding partners into plurality of nanowells for analysis (page 780, right column, first paragraph). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Jorgenson et al. with the plurality of microfluidic channels and fluorescent tagged binding partners

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as taught by Delmarche et al. for large-scale tests in a plurality of samples in nanowell for efficiency, economy and reproducibility analysis.

6. Claims 84-87, 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson et al in view of Delmarche et al. as applied to claims 82-83, 95-96 above, and further in view of Fukushima et al. (US 5113470).

Both Jorgenson and Delmarche et al. references have been discussed but do not specifically teach the structure of waveguide or cladding layer as a sheet or film strips for detection purposes. Fukushima et al. teach an optical waveguide device comprising a plurality of optical waveguides with cladding layers extending adjacent each other in a sheet-like form (See Abstract; Figure 1 and 2). Fukushima et al. teach that the sheet-like structure of the core-waveguide and cladding layer provides advantages of high image resolution, high transmission efficiency, low manufacturing cost and minimizing crosstalk among waveguides (Col. 2, line 6-25; Col. 3, line 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided both Jorgenson and Delmarche et al. with the sheet-like structures of waveguides and cladding layers as taught by Fukushima et al. since it is known in the analogous art to increase image resolution, high transmission and minimize crosstalk among core-waveguide for low cost.

With respect to claim 86, and 99, applicant recites the film comprises width of 8, 16, or 32 mm. As discussed in this Office Action (See Paragraph #2), it is not clear whether this "width" refers to the "thickness". Furthermore, the microfluidic device taught by Delmarche et al. falls within size ranges of 3mm by 1 mm dimensions (See page 796, right column, second paragraph). Therefore, it would have been obvious to one having ordinary skilled in the art at the time the invention was made to vary the waveguide/cladding layer size to optimize detection condition since it has been held discovering the optimum or workable ranges involving only routine skilled in the art. In re Aller, 105 UPSQ 233.

Response to Applicant's Arguments

7. Applicant's arguments with respect to claims 2-6, 12-14, 16, 18-20, 26-32, 34, 41, 43, 45, 47, 53, 56, 58, 64-81 have been considered but are moot in view of the cancellation and new ground(s) of rejection.

Allowable Subject Matter

8. Claims 90-94 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is an examiner's statement of reasons for allowance: no prior art fairly suggests or teaches a biosensor with structure of combination with an outer top layer containing at least one port, a fluidic layer having at least one fluidic channel below said top outer layer where a first cladding layer containing at least one micro-cuvette in fluid communication with the fluidic channel, and a core waveguide in contact with the micro-cuvette and a second cladding layer in contact with the core waveguide. The closest prior art is Jorgenson et al., (US 5835645) , however, Jorgenson et al. do not contain the structure of placing the cladding (1)-waveguide-cladding layers (2) below a fluidic layer where the first cladding layer having micro-cuvette in fluid communication with the fluidic channel.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

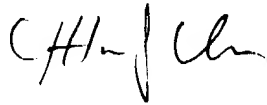
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Jacob Cheu

Examiner

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September 27, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/15/04